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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,278	07/09/2003	Frank Daniel Long	1341-2	2088
23869	7590	10/20/2004	EXAMINER	
HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791			KRISHNAN, GANAPATHY	
			ART UNIT	PAPER NUMBER

1623

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/616,278

Applicant(s)

LONG ET AL.

Examiner

Ganapathy Krishnan

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-64 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

Art Unit: 1623

DETAILED ACTION

The amendment filed 7/27/2004 has been received, entered and carefully considered.

The following information provided in the amendment affects the instant application:

1. Claims 1-4, 8-9, 12, 20, 43-55 and 59-64 have been amended.
2. Remarks drawn to rejections under 35 USC 112, second paragraph, 102(b) and 103(a)

Claims 1-64 are pending in the case.

The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The rejection of claims 25-28, 47-50, 59, 60 and 64 under 35 USC 112, second paragraph has been overcome by amendment.

Claim Rejections - 35 USC § 102

Claims 1-11, 43-46, 61 and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Balazs (US 4141973); Claims 12-16, 50, 51, 59 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Henderson et al (US 6255295); Claims 20-28 and 35-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Osuji (Biochimica et Biophysica Acta, 1971, 244, 481-483); Claims 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Bracke et al (US 4517295); Claims 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Sakurai et al (US 4716224); Claims 52-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Henderson et al (US 6255295) are maintained for reasons of record.

Art Unit: 1623

Applicants argue that the prior art in all of the the instant rejections do not disclose a hyaluronic acid rich fraction isolated from eggshell membrane. Applicants' arguments are not found to be persuasive.

The instant claims are drawn to compositions comprising hyaluronic acid and the composition further comprising chondroitin sulfate and a hexosamine and a method for producing the said composition. The prior art above all teach compositions comprising hyaluronic acid and also method of producing hyaluronic acid as instantly claimed including Osooji who discloses the presence of chondroitin sulfate (abstract and page 482, 37-39). The source of the said hyaluronic acid is not given patentable weight.

Claim Rejections - 35 USC § 103

Claims 17-19 and 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson (US 6255295); Claims 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osooji (Biochimica et Biophysica Acta, 1971, 244, 481-483) in combination with Baker et al (Biochemical Journal, 1962, 82, 352-361); Claims 61, 63 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balazs (US 4141973) in combination with Henderson et al (US 6255295) are maintained for reasons of record.

Applicants argue that although Henderson et al disclose that the composition can include hyaluronic acid, they do not disclose a composition that includes both hyaluronic acid and chondroitin sulfate as required by claims 17-19. Applicants also argue that Henderson's composition does not include an eggshell membrane fraction rich in hyaluronic acid naturally

Art Unit: 1623

occurring in eggshell membrane. This argument is also advanced by the applicants for the rejection of claims 40-42 and 61, 63 and 64. This is not found to be persuasive.

In response to applicant's argument the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In the instant case Henderson et al need not necessarily disclose a composition comprising hyaluronic acid, a hexosamine and chondroitin sulfate. Henderson et al teach a composition comprising hyaluronic acid and glucosamine (a hexosamine) and a composition comprising chondroitin sulfate and glucosamine. Based on this teaching it would be obvious to one of ordinary skill in the art to make a composition comprising hyaluronic acid and chondroitin sulfate. The source of the hyaluronic acid (eggshell membrane) is not given patentable weight. Hence, the rejection of the instant claims is being maintained.

Conclusion

Claims 1-64 are rejected

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

Art Unit: 1623

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK

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